K140948

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510(k) Summary

BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay on the BD Viper LT System

MAY 2 0 2014

Applicant	BD Diagnostic Systems 7 Loveton Circle Sparks, MD 21152
Establishment Registration No.	1119779
Contact Person	Sherma Winston, M.S., RAC tel. 410-316-4145 fax. 410-316-4188 sherma_winston@bd.com
Summary Date	May 15, 2014
Proprietary Name	BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay
Generic Name	DNA probe, nucleic acid amplification, Neisseria
Classification	Class II
Classification Name	Neisseria spp. direct serological test reagents
Regulation Number	866.3390
Product Code	LSL

Predicate Device
The BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay (BD ProbeTec GCQ Assay) was cleared for use with the predicate BD Viper System in extracted mode via K081825.

Device Description

The BD ProbeTec GCQ Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescently-labeled detector probe The reagents for strand displacement amplification (SDA) are dried in two separate disposable microwells: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. In alignment with the FDA Guidance Document, "*Assay Migration Studies for In Vitro Diagnostic Devices, Guidance for Industry and FDA Staff*", April 25, 2013 the BD ProbeTec GCQ Assay is being migrated from the existing BD Viper System operating in extracted mode (Viper XTR) to the new BD Viper LT System.

The BD Viper LT System is a table-top instrument that is designed to be fully contained on a standard laboratory bench-top. The system performs automated extraction of nucleic acids from

multiple specimen types in addition to amplification and detection of target nucleic acid sequences when utilized with legally marketed in vitro diagnostic assays.

Intended Use

The BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay, when tested with either the BD Viper™ System in Extracted Mode or the BD Viper™ LT System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.

Comparison to Predicate Device

A comparison of the BD ProbeTec GCQ Assay on the BD Viper LT System with the predicate BD Viper System is summarized below.

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BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay on the BD Viper LT System

Table 1 Comparison to Predicate Device

Item	BD ProbeTec GCQ Assay on the BD Viper System (K081825)	BD ProbeTec GCQ Assay on the BD Viper LT System (K140448)
Device Class	II	II
Regulation Specialty	Microbiology	Microbiology
Assay Results	Qualitative	Qualitative
Type of Assay	Molecular NAAT	Molecular NAAT
Intended Use	The BD ProbeTec (GC) Q^x Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.	The BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay, when tested with either the BD Viper™ System in Extracted Mode or the BD Viper™ LT System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.
Technology	Strand Displacement Amplification (SDA)	same
Specimen Types	**Female specimens:** endocervical swab patient-collected vaginal swab neat urine UPT urine	**Female specimens:** endocervical swab patient-collected vaginal swab neat urine UPT urine LBC specimens collected in SurePath Preservative Fluid

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BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay on the BD Viper LT System

Item	BD ProbeTec GCQ Assay on the BD Viper System (K081825)	BD ProbeTec GCQ Assay on the BD Viper LT System (K140448)
	Male specimens: urethral swab neat urine UPT urine	LBC specimens collected in PreservCyt Solution **Male specimens:** urethral swab neat urine UPT urine
Priming Microwell		
Primers	Target a sequence within the GC pilin gene inverting protein homologue	Same
Detector	Linear, analyte-specific Detector Probe • Fluorescein (fluorophore) • Dabcyl (quencher)	Same
Nucleotides	4 nucleotides required for SDA	Same
Non-specific reagents and cofactors	Buffering components, magnesium ions, salt and stabilizing reagents	Same
Amplification Microwell		
Restriction Enzyme	*Bso*BI restriction enzyme	Same
Polymerase	*Bst* DNA polymerase	Same
Non-specific reagents and cofactors	Buffering components, magnesium ions, salt and stabilizing reagents	Same
Assay Buffer	Bicine-potassium hydroxide-based	Same

Analytical Performance Characteristics

The BD ProbeTec GCQ Assay formulation for the BD Viper LT System has not changed from that used with the BD Viper System in extracted mode. Studies were conducted to support analytical performance of the BD Viper LT System.

System Contamination

A study was conducted to evaluate the risk of producing a false positive result in either the same run on the BD Viper LT System or in a subsequent run. Negative and positive samples were tested on each of three BD Viper LT Systems. Negative samples consisted of Q^x Swab Diluent or LBC Specimen Dilution Tube with LBC Specimen Matrix (PreservCyt LBC media). Positive samples consisted of a representative analyte (at 10^5 CT EB/mL) spiked into Q^x Swab Diluent or LBC Specimen Dilution Tube with LBC Specimen Matrix. The overall rate of contamination (i.e., with alternating columns of positive and negative samples and a prevalence of 50%) was 0.32% (2/630) for Q^x Swab Diluent and 0.0% (0/630) for LBC Specimen Matrix. Contamination rates across the three BD Viper LT Systems are summarized in **Table 2**.

Table 2 System Contamination

BD Viper LT System	Q^x Sample Diluent			LBC Specimen Matrix		
	n	Positive Results	Percent Positive	n	Positive Results	Percent Positive
1	210	0	0.00%	210	0	0.00%
2	210	1	0.48%	210	0	0.00%
3	210	1	0.48%	210	0	0.00%
Overall	630	2	0.32%	630	0	0.00%

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BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay on the BD Viper LT System

Clinical Performance Characteristics

The BD ProbeTec GCQ Assay formulation for the BD Viper LT System has not changed from that used with the BD Viper System in Extracted Mode. The following studies were conducted to support clinical performance of the BD Viper LT System.

Clinician-collected BD SurePath and PreservCyt specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female Q^x UPT urine specimens were collected from 653 female subjects and 170 male subjects attending OB/GYN, sexually transmitted disease (STD) and family planning clinics at four geographically diverse clinical sites in North America. Subjects were classified as symptomatic if symptoms were reported by the subject. The final data analysis included 617 compliant female subjects and 167 compliant male subjects. All specimens were shipped to BD on cold packs for specimen screening, aliquoting, and comparison panel assembly.

Each comparison panel consisted of randomly chosen positive and negative specimens (based on BD Viper System in extracted mode reference results). The positive and negative specimens were randomized within the panel, and labeled such that the instrument user was blinded to the specimen results. Panels were identical across all of the BD Viper LT test sites. The blinded comparison panels were sent to the 3 external sites for testing on the BD Viper LT System and one internal site for testing using the BD Viper System in extracted mode with the BD ProbeTec GC Q^x Assay.

BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay on the BD Viper LT System

Table 3: PPA and NPA for the BD ProbeTec GCQ Assay on the BD Viper LT System

			Positive Percent Agreement		Negative Percent Agreement	
Gender	Specimen Type	Site	Percent	95% CI	Percent	95% CI
Female	Vaginal Swab	A	100.0% (27/27)	(87.5%, 100.0%)	94.9% (75/79)	(87.7%, 98.0%)
		B	96.3% (26/27)	(81.7%, 99.3%)	96.2% (76/79)	(89.4%, 98.7%)
		C	96.3% (26/27)	(81.7%, 99.3%)	96.2% (76/79)	(89.4%, 98.7%)
		Total	97.5% (79/81)	(92.6%, 100.0%)	95.8% (227/237)	(92.0%, 98.7%)
	Q^x UPT	A	96.3% (26/27)	(81.7%, 99.3%)	100.0% (79/79)	(95.4%, 100.0%)
		B	100.0% (27/27)	(87.5%, 100.0%)	100.0% (79/79)	(95.4%, 100.0%)
		C	96.3% (26/27)	(81.7%, 99.3%)	100.0% (79/79)	(95.4%, 100.0%)
		Total	97.5% (79/81)	(92.6%, 100.0%)	100.0% (237/237)	NA
	SurePath	A	96.4% (27/28)	(82.3%, 99.4%)	100.0% (78/78)	(95.3%, 100.0%)
		B	96.4% (27/28)	(82.3%, 99.4%)	100.0% (78/78)	(95.3%, 100.0%)
		C	96.4% (27/28)	(82.3%, 99.4%)	98.7% (77/78)	(93.1%, 99.8%)
		Total	96.4% (81/84)	(89.3%, 100.0%)	99.6% (233/234)	(98.7%, 100.0%)
	PreservCyt.	A	100.0% (27/27)	(87.5%, 100.0%)	100.0% (79/79)	(95.4%, 100.0%)
		B	100.0% (27/27)	(87.5%, 100.0%)	100.0% (79/79)	(95.4%, 100.0%)
		C	100.0% (27/27)	(87.5%, 100.0%)	100.0% (79/79)	(95.4%, 100.0%)
		Total	100.0% (81/81)	NA	100.0% (237/237)	NA
	All	Total	97.9% (320/327)	(95.1%, 100.0%)	98.8% (934/945)	(97.9%, 99.6%)
Male	Q^x UPT	A	100.0% (40/40)	(91.2%, 100.0%)	100.0% (73/73)	(95.0%, 100.0%)
		B	100.0% (40/40)	(91.2%, 100.0%)	100.0% (73/73)	(95.0%, 100.0%)
		C	100.0% (40/40)	(91.2%, 100.0%)	98.6% (72/73)	(92.6%, 99.8%)
		Total	100.0% (120/120)	NA	99.5% (218/219)	(98.6%, 100.0%)
Total	All	Total	98.4% (440/447)	(96.4%, 100.0%)	99.0% (1152/1164)	(98.1%, 99.6%)

Reproducibility

Reproducibility of the BD Viper LT System using the BD ProbeTec GCQ Amplified DNA Assay was evaluated at three test sites (two external clinical sites and one internal site) on one BD Viper LT System per site. Panels comprised of three levels of CT and GC organisms seeded into LBC specimen matrix (0.5 mL spiked into LBC Dilution Tubes for the BD ProbeTec Q^x Amplified DNA Assays), vaginal matrix in Q^x Swab Diluent (containing a clean male urethral swab), and urine specimen matrix (in Q^x UPT). CT and GC organisms were spiked into each specimen matrix. Uninoculated LBC specimen matrix, vaginal matrix in Q^x diluent, and urine matrix were used as negative samples. Two operators per site performed the BD Viper LT reproducibility study. Both operators ran one panel each day, over a total of eight days. A total of sixteen runs, each composed of 8 LBC, 8 swab and 8 UPT panel members described above were performed at each of two external BD Viper LT test sites and one internal BD Viper LT test site. The data are summarized in **Table 4.**

BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x
Amplified DNA Assay on the BD Viper LT System

Table 4: Summary of Reproducibility Data on the BD Viper LT System for the BD ProbeTec GCQ Assay.

					Within Run		Between Run within Day		Between Day within Site		Between Site		Total	
Specimen Type	Panel	% Correct	95% CI	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
LBC	Negative	100.0% (96/96)	(96.2 - 100.0%)	3.3	9.2	280.1%	0.0	0.0%	0.0	0.0%	2.2	65.4%	9.5	287.6%
	High Negative	20.8% (20/96)	(13.9 - 30.0%)	560.2	425.0	75.9%	49.0	8.7%	0.0	0.0%	0.0	0.0%	427.8	76.4%
	Low Positive	100.0% (96/96)	(96.2 - 100.0%)	1415.9	231.4	16.3%	172.0	12.1%	0.0	0.0%	28.1	2.0%	289.7	20.5%
	Moderate Positive	100.0% (94/94)	(96.1 - 100.0%)	1631.9	169.7	10.4%	93.7	5.7%	70.9	4.3%	0.0	0.0%	206.4	12.6%
Swab	Negative	99.0% (95/96)	(94.3 - 99.8%)	41.6	180.1	432.6%	13.2	31.6%	0.0	0.0%	0.0	0.0%	180.6	433.8%
	High Negative	13.5% (13/96)	(8.1 - 21.8%)	871.5	562.4	64.5%	0.0	0.0%	0.0	0.0%	88.2	10.1%	569.2	65.3%
	Low Positive	100.0% (95/95)	(96.1 - 100.0%)	1687.5	297.7	17.6%	0.0	0.0%	0.0	0.0%	34.7	2.1%	299.7	17.8%
	Moderate Positive	100.0% (96/96)	(96.2 - 100.0%)	1819.2	163.3	9.0%	48.2	2.7%	43.3	2.4%	73.3	4.0%	190.3	10.5%
UPT	Negative	100.0% (96/96)	(96.2 - 100.0%)	3.6	8.0	221.8%	0.0	0.0%	0.0	0.0%	0.0	0.0%	8.0	221.8%
	High Negative	18.8% (18/96)	(12.2 - 27.7%)	766.6	502.1	65.5%	0.0	0.0%	75.8	9.9%	15.8	2.1%	508.0	66.3%
	Low Positive	100.0% (96/96)	(96.2 - 100.0%)	1593.6	224.9	14.1%	86.6	5.4%	36.7	2.3%	0.0	0.0%	243.8	15.3%
	Moderate Positive	100.0% (96/96)	(96.2 - 100.0%)	1741.5	126.1	7.2%	86.2	5.0%	35.1	2.0%	21.5	1.2%	158.2	9.1%

Conclusions

The analytical and clinical study results for the BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay tested on the BD Viper LT System support the determination of substantial equivalence in accordance with the intended use as stated in the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Becton, Dickinson and Company
Sherma Winston, M.S., RAC
7 Loveton Circle
Sparks, MD 21152

May 20, 2014

Re: K140448
Trade/Device Name: BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. direct serological test reagents
Regulatory Class: II
Product Code: LSL
Dated: February 20, 2014
Received: February 21, 2014

Dear Ms. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tamara V. Feldblyum -S for

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K140448

Device Name: BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

Indications for Use:

The BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay, when tested with either the BD Viper™ System in Extracted Mode or the BD Viper™ LT System, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid or PreservCyt™ Solution using an aliquot that is removed prior to processing for either the BD SurePath or ThinPrep™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Tamara V. Feldblyum -S
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